DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0503]

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Certifier <u>R</u> .	LEDESMA

Draft Compliance Policy Guide: "Filth from Insects, Rodents, and Other Pests in Food;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft compliance policy guide (CPG) currently entitled "Filth from Insects, Rodents, and Other Pests in Food." The purpose of this draft CPG is to revise, clarify, and redefine existing guidance on the interpretation of filth in foods within the context of current science. The draft CPG will provide written guidance to FDA components as well as to the industry.

DATES: Submit written or electronic comments on this draft CPG by [insert date 60 days after date of publication in the Federal Register].

ADDRESSES: Submit written requests for single copies of the draft CPG "Filth from Insects, Rodents, and Other Pests in Food" to the Director, Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request, or FAX your request to 301–827–0482. See the SUPPLEMENTARY INFORMATION section for electronic access to the document.

Submit written comments on the draft CPG to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT:

Technical Questions Concerning Filth in Foods: Alan R. Olsen, Microanalytical Branch (HFS—315), Office of Plant, Dairy Foods, and Beverages, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202—205—4438, FAX 202—205—4091.

Questions Concerning Regulatory Actions: MaryLynn Datoc, Division of Compliance Policy (HFC-230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0413, FAX 301–827–0482.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has developed a draft CPG to revise, clarify, and redefine existing guidance on foods that contain filth from insects, rodents, and other pests to reflect recent advances in science. The purpose of this draft CPG is to provide clear policy to FDA's field and headquarters staff with regard to filth from insects, rodents, and other pests in foods. It also contains information that may be useful to the regulated industry and to the public.

The draft CPG, when finalized, will supersede the current CPG and represents the agency's current thinking on the subject. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such an approach satisfies the requirements of applicable statutes or regulations.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115).

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the draft CPG entitled "Filth from Insects, Rodents, and Other Pests in Food." Two copies of any comments are to be submitted, except that individuals may submit

one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft CPG and received comments may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Copies of the draft CPG may also be downloaded to a personal computer with access to the Internet. The Office of Regulatory Affairs home page includes the draft CPG and may be accessed at http://www.fda.gov/ora under "Compliance References."

Dated: 12/11/01

December 11, 2001.

Dennis E. Baker,

Associate Commissioner for Regulatory Affairs.

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